

REMARKS

Claims 1, 20, 21, 23, 24, 26 and 33-43 are currently pending on entry of the amendments above. Claims 2-19, 22, 25 and 27-32, have been cancelled without prejudice or disclaimer and Applicants reserve the right to pursue the subject matter of these claims in related applications.

Claims 33-43 have been added to expand the embodiments of the provisionally elected group (see below). New claims 33-43 are completely supported by the specification and claims as originally filed, for example, at page 19, line 23 through page 20, line 1; at page 31, line 22 through page 33, line 10; at page 127, line 23 through page 128, line 19; at page 132, lines 21-27; and claims 1, 20, 22 and 26 as originally filed. Accordingly, no new matter has been introduced.

I. Restriction Requirement

The Examiner has required an election under 35 U.S.C. § 121 of one of the following groups:

- I. Claims 1-19, drawn to nucleic acids, vectors, host cells and method for making protein recombinantly, ...
- II. Claim 20, drawn to polypeptides, ...
- III. Claims 21 and 22, drawn to antibodies to the polypeptides of Group II, ...
- IV. Claims 23, 25, 31 and 32, in so far as they are drawn to a method of treatment by administration of the polypeptides of Group II, ...
- V. Claims 23, 27 and 29-32, in so far as they are drawn to a method of treatment by administration of antibodies of Group III, ...
- VI. Claims 24 and 26, in so far as they are drawn to a method of diagnosis comprising contacting the polypeptides of Group II with a biological sample and assaying for binding, ...
- VII. Claims 24 and 28, in so far as they are drawn to a method of diagnosis comprising contacting the antibodies of Group III with a biological sample and assaying for binding,

for examination. See, Paper No. 7, pages 2-3.

The Examiner contends that the inventions are distinct, each from the other.

In order to be fully responsive, Applicants provisionally elect, *with traverse*, the subject matter of Group VI as represented by originally filed claims 24 and 26, and drawn to a method of diagnosis comprising contacting the polypeptides of Group II with a biological sample and assaying for binding, for further prosecution. Applicants reserve the right to file one or more divisional applications directed to non-elected inventions should the restriction requirement be made final. Additionally, should the present restriction requirement be made final, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants point out that claims 2-19, 22, 25 and 27-32 have been canceled and that new claims 33-43 are directed to subject matter falling within the ambit of Group VI as cast by the Examiner.

Applicants respectfully traverse and request the withdrawal of the Restriction Requirement.

As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the groups listed by the Examiner represented distinct or independent inventions, restriction remains improper unless it can be shown

that the search and examination of both groups would entail a “serious burden.” *See* M.P.E.P. § 803.

In the present situation, no such showing has been made. Although the Examiner has argued that Groups I through VII are separately classified, Applicants nonetheless submit that a search of the claims of Group I would also provide useful information for the claims of Groups II-III, while a search of the claims of Group II would also provide useful information for the claims of Groups IV and VI and a search of Group III would also provide useful information for the claims of Groups V and VII. For example, in many if not most publications disclosing a polynucleotide, the authors also routinely include polypeptides encoded thereby. Since the searches for polynucleotides and polypeptides commonly overlap, the search and examination of a polynucleotide and the corresponding polypeptides would not entail a serious burden.

Applicants also respectfully point out that the Examiner has classified Groups VI and VII in the same class and subclass (class 436, subclass 501), so that contrary to the Examiner’s assertion, they have not “acquired a separate status in the art as shown by their different classification,” and would not present a serious burden to search and examine together. *See* Paper 7, page 5.

Accordingly, in view of M.P.E.P. § 803, the claims of all Groups I-VII should be searched and examined in the present application. Applicants therefore respectfully request that the restriction requirement under 35 U.S.C. § 121 be reconsidered and withdrawn, and that the instant claims be examined in one application.

II. Election of Species

The Examiner has held that the claims of Groups IV-VII are directed to distinct species and has required that Applicant elect a single species for further prosecution. The

Examiner alleges that “[t]his application contains claims directed to the following patentably distinct species of the claimed invention: A) an immunodeficiency or condition associated with an immunodeficiency, or B) an autoimmune disease or condition associated with an autoimmune disease.” *See*, Paper No. 7, page 6.

The Examiner has further held that such claims drawn to the diagnosis of an immunodeficiency or condition associated with an immunodeficiency, or an autoimmune disease or condition associated with an autoimmune disease are further directed to distinct species and has required that Applicant elect a single species for further prosecution. The Examiner states that “Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of autoimmune disease from those listed in claims 25-28.” *See*, Paper No. 7, page 6.

Applicants respectfully point out that the Examiner has not disclosed any statutory or regulatory basis for the requirement for election of species within the provisionally elected Group VI. However, in order to be fully responsive, Applicants hereby further provisionally elect the subject matter of Group VI as it is drawn to the diagnosis of an autoimmune disease or condition associated with an autoimmune disease, wherein that autoimmune disease or condition associated with an autoimmune disease is Sjögren’s syndrome, and claimed in original claim 26. Applicants understand the elected species to be read upon by original claim 26 and new claims 33-43.

Applicants note that the Examiner is requiring an election of a species member of the Markush-type claims. Applicants respectfully point out that MPEP § 803.02 requires that “[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits.” As described above, the members of the Markush groups of the pending claims to provisionally elected Group VI

are sufficiently few in number and very closely related, as they are all different *autoimmune diseases*, so that a search of all of the members may be made without a serious burden. Moreover, even assuming that examination of the entire claim would present a serious burden, MPEP § 803.02 states that “[f]ollowing election, the Markush-type claim will be examined fully as to the elected species and further to the extent necessary to determine patentability.” If no prior art is found “that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended.” *Id.* (emphasis added).

Applicants also note that the Examiner has identified claims 31 and 32 as generic claims directed to autoimmune diseases and conditions associated with autoimmune diseases. *See*, Paper No. 7, page 6. Neither claim 31 or 32 is directed to a method of detecting or diagnosing any autoimmune disease or condition associated therewith, therefore neither claim is generic to any identified species falling within the ambit of Group VI as drawn by the Examiner. Indeed the MPEP states that “a generic claim should include no material element additional to those recited in the species claims, and must comprehend within its confines the organization covered in each of the species.” *See*, M.P.E.P. § 806.04(d). Accordingly, Applicants maintain that claims 31 and 32 are not generic to any of the species identified or referred to by the Examiner. Therefore, keeping in mind the explicit teaching of the M.P.E.P., Applicants believe that claim 26 is the appropriate generic claim encompassing the subject matter elected in the present response. Applicants respectfully request clarification of this matter from the Examiner.

In a telephone call of August 6, 2002, the Examiner maintained the position that claim 26 is not a generic claim directed to subject matter within Group VI as provisionally elected. Therefore, Applicants submit that no genus has been described and therefore no

species can be described within Group VI as defined by the Examiner. Accordingly, the requirement for an election of species is improper and should be withdrawn.

In view of the discussion above, Applicants respectfully request that the restriction requirement under 35 U.S.C. § 121 and the further requirement for election of species within Group VI be withdrawn and the instant claims be examined in one application. Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the file history of the instant application.

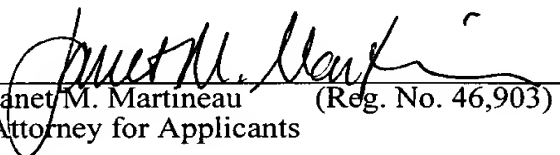
Conclusion

In view of the foregoing remarks, applicants believe that this application is now in condition for substantive examination. The Examiner is invited to call the undersigned at the phone number provided below if any further action by applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Enclosures
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